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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,852	08/27/2003	Robert Joseph Isfort	8448R	7224

27752 7590 10/07/2005

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EXAMINER	
SHAFER, SHULAMITH H	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,852	ISFORT ET AL.	
	Examiner	Art Unit	
	Shulamith H. Shafer, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *11-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-10* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/07/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SPD

Detailed Action

Status of Application, Amendments, And/Or Claims

Applicants' response of 8 August 2005 has been entered in full. Claims 1-18 are pending in the present application. The Information Disclosure Statement (IDS) filed on 7 January 2004 has been entered in full. References to Foreign Patent Documents have been lined through and not considered because they have not been supplied as required by IDS rules. There have been no amendments to the claims, no addition of new claims and no cancelled claims.

Election/Restriction

Applicants' election of Invention I (claims 1-10) in the reply filed on 8 August 2005 is acknowledged. This election has been made with traverse as it is considered by Applicants to be improperly made. Applicants' arguments have been fully considered but are not found to be persuasive for the following reasons:

Applicants' argument that maintaining the restriction requirements will result in a piece-meal prosecution is an improper one. MPEP rules regarding piece-meal prosecution (MPEP §707.07 (g)) are directed to the rejection of each claim on all valid grounds available, not the prosecution of separate and distinct inventions. Applicants may be assured that all patentability issues relevant to the elected claims will be addressed in the first action, thereby avoiding piece-meal prosecution.

Applicants' argument that the restrictions do not impose an undue search burden as the search appears to involve searching only two classes (namely 530 and 514) are not persuasive. The Examiner's search will include not only the United States patent literature, but the foreign patent literature and non-patent literature as well. The search of the patent and non-patent literature will not be restricted by classification.

The Examiner has required restriction between process and composition (product) claims. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. PTO practice in view of *In re Ochiai* is directed to rejoinder of claims after allowable

subject matter has been indicated, and not to withdrawal of restriction requirement. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). However, as applicants have chosen to elect a method, and not a product, rejoinder in view of the *Ochiai* decision is not applicable to this claim.

The claims of Inventions I and II are directed to identifying compounds that bind or activate vertebrate CRF2R (Invention I) and regulate skeletal muscle mass or function *in vivo* (Invention II). Claim 11 of Invention II requires an additional search and consideration of patient population not required by the first group. Therefore, restriction between these two groups of inventions is deemed proper as involving an undue burden on the Examiner.

Applicants' argue that the sequences claimed in claims 1-10 are genes and proteins that encode CRF2R receptors from various vertebrate species, share a high level of homology, and are conserved across vertebrate life forms. However, while there may be shared structures between the sequences, there is no single sequence search that would identify prior art relevant to all of the listed sequences. Therefore, requirement for election of a single disclosed species is deemed proper.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 11-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims.

Claims 1-10 are under examination to the extent they read on the elected invention.

Objections:

Figures 3A and 3B indicate "denervated leg" as indicated by hatch-marked columns. However, no columns with hatch marks are shown in the figures. The Brief Description of the Figures and Tables (page 10) describe Figures 3A and B as demonstrating the anti-atrophy effect of sauvagine on glucocorticoid-induced atrophy of

the tibialis anterior muscle (Fig 3A) and the medial gastrocnemius muscle (Fig 3B). The description of the figures does not indicate a "denervated leg" atrophy model. Appropriate correction is required.

The disclosure is objected to because of the following informalities: The use of the trademark FLEXX (page 57), DMEM (page 41), MEM (page 42) HBSS and Luciferase Assay Buffer and Luciferase Assay Substrate (page 43) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Appropriate correction is required.

Objection to claim:

Claim 3 is objected to as being drawn to non-elected inventions. Appropriate correction is required.

Information Disclosure Statement

The information disclosure statement filed on 7 January 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document. References to foreign patent documents have been lined through and not considered because documents were not provided to this Office.

Journal articles by Thomas et al. (Reference 12), and McCarthy et al. (Reference 15), were improperly cited by Applicant and therefore lined through and not considered. Reference 12 does not include a Volume number and year. Reference 16 does not include the year of publication.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 5, 7-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6-17 of U. S. Patent 6,670,140 B2.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, for example, *In re Berg*, 140 F.3d 1428 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. The patented claims (U. S. Patent 6,670,140 B2) disclose a method for identifying candidate compounds for regulating skeletal muscle mass or function comprising contacting a CRF_2R and determining whether the

test compound binds to the CRF_2R (Claim 1) or activates (Claim 6) the CRF_2R. These two claims render Claim 1 of the instant invention obvious. Claim 13 of the patent discloses a method for identifying candidate compounds by measuring cellular cAMP levels by measuring expression of a reporter gene associated with a cAMP responsive element. Claim 13 renders Claim 5, which recites a method for identifying candidate compounds by measuring cellular cAMP levels by measuring expression of a reporter gene associated with a cAMP responsive element, of the instant invention obvious. Therefore, Claims 1, 2, 4, 5, 7-10 are all rendered obvious by the cited claims in the patent.

Claim 6 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 13 in U. S. Patent 6,670,140 in view of McDonnell et al. (1998, Br Jnl of Pharmacology, 125:717). Claim 13 of the patent discloses a method for identifying candidate compounds by measuring cellular cAMP levels by measuring expression of a reporter gene associated with a cAMP responsive element. Claim 6 of the instant invention recites identifying candidate compounds in which the reporter gene is alkaline phosphatase, chloramphenicol acetyltransferase, luciferase, glucuronide synthetase, growth hormone, placental alkaline phosphatase or Green Fluorescent Protein. McDonnell et al. teaches the construction of a reporter gene construct containing six copies of the consensus cyclic AMP response element (CRE) subcloned upstream of the minimal HSV-TK promoter and used to promote expression of secreted placental alkaline phosphatase (sPAP) (page 718, column 1 "*Construction of p6CRE-sPAP-Hyg*" and page 718, Figure 1). It would be obvious to the skilled artisan to monitor cyclic AMP generation by using one of the disclosed reporter genes under control of a CRE. The person of ordinary skill in art reasonably would have expected success because McDonnell et al teaches the construction of a reporter gene construct associated with a cAMP responsive element and teaches its use to meaure cAMP generation in response to activation of the β_2-adrenoceptor (see, for example, Table 3 and Figure 3 on page 721).

Art cited as of interest:

The prior art made of record and not relied upon that is considered pertinent to applicant's disclosure is Dautzenberg et al (J Neurochemistry 69:1640, 1997). Dautzenberg et al. disclose a Xenopus CRF receptor (page 1642, column 2, second paragraph and page 1643, Figure 1) having 100% homology to the CRF_2R receptor of SEQ ID NO:32. Dautzenberg et al. (page 1642, column 2, paragraph 3, and page 1644, paragraph 4) teach radioreceptor binding assays utilizing HEK 293 cells expressing CRF-R2 receptors involving contacting different CRF analogues with isolated membranes of transfected cells and determining their capability to displace iodinated h/rCRF, thereby measuring binding of test compound with receptor. In addition, Dautzenberg et al. teach an assay detecting receptor activation by contacting HEK 293 cells stably transfected with CRF-R2 with increasing concentrations of CRF analogues and measuring cAMP accumulation (page 1643, column 2 and 1645, Figure 3) thus measuring the activation of the receptor by contact with a test compound. However, Dautzenberg et al do not disclose a relationship between activation of CRF-R2 and increasing muscle mass or function in a skeletal muscle atrophy system.

Conclusions:

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D. can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

SHS

ELIZABETH KEMMERER
PRIMARY EXAMINER